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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,147	11/17/2000	Shuji Hinuma	47176-DIV2 (342)	7219
7590 01/21/2004			EXAMINER	
DAVID G. CONLIN EDWARDS AND ANGELL,LLP P.O. BOX 9169 BOSTON, MA 02209			ROMEO, DAVID S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/716,147

Applicant(s)

HINUMA ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/776,971.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1100
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 17, 21-23 are pending. In a telephone conversation on June 18, 2003 John B. Alexander confirmed that by stating "18.20. (Cancelled)" in the amendment filed June 5, 2003 it was intended that claims 18-20 be cancelled.

5

Applicant's election of group III, claims 17, 21, 22, 23, to the extent that they are drawn to drawn to a measuring or testing process involving ligand-receptor binding wherein the ligand comprises SEQ ID NO: 73 and the receptor comprises SEQ ID NO: 21, in the paper filed 09/15/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

10

Upon further consideration the restriction requirement mailed 08/11/2003 is revised as follows. In view of the fact that the all of the claims to the extent that they are drawn to the invention elected in the paper filed 09/15/2003 are within group I of the revised restriction requirement below, group I of the revised restriction requirement is being examined on the merits.

15

Revised Election/Restrictions

20

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 17, 21-23, to the extent that they are drawn to drawn to a measuring or testing process involving ligand-receptor binding wherein the ligand comprises SEQ ID NO: 73 and the receptor comprises SEQ ID

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NO: 19, SEQ ID NO: 20, or SEQ ID NO: 21, classified in class 435, subclass 7.1.

- II. Claims 17, 21, 22, to the extent that they are drawn to a measuring or testing process involving ligand-receptor binding wherein the ligand comprises SEQ ID NO: 73 and the receptor comprises SEQ ID NO: 22, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The following pairwise combinations of methods are independent and distinct, wherein each member of a pair uses different starting materials: I and II. In addition SEQ ID NO: 19, SEQ ID NO: 20, and SEQ ID NO: 21 are different from SEQ ID NO: 22. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such polypeptide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 17, 21, 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) to the extent that they are drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 09/15/2003.

5

Applicant's request to rejoin the remaining groups upon the allowance of the elected group is acknowledged. However, in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), process claims, which do not depend from or otherwise include all the limitations of the allowable product, are not subject to being
10 rejoined. It is noted that SEQ ID NO: 19 and SEQ ID NO: 20 are subfragments of SEQ ID NO: 21. As such, SEQ ID NO: 19 and SEQ ID NO: 20 could never be subject to rejoinder because they could never depend from or otherwise include all the limitations of SEQ ID NO: 21. SEQ ID NO: 22 is different from SEQ ID NO: 19, SEQ ID NO: 20, or SEQ ID NO: 21. As such, SEQ ID NO: 22 does not depend from or otherwise include
15 all the limitations of SEQ ID NO: 19, SEQ ID NO: 20, or SEQ ID NO: 21 and is not subject to being rejoined.

Claim Objections

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent
20 form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. SEQ ID NO: 3, SEQ ID

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NO: 4, SEQ ID NO: 5, SEQ ID NO: 8, SEQ ID NO: 47, SEQ ID NO: 50, SEQ ID NO: 61, and SEQ ID NO: 64 do not infringe and fail to further limit SEQ ID NO: 73.

Claim Rejections - 35 USC § 112

5 The following is a quotation of the first paragraph of 35 U.S.C. 112:

 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10

 Claims rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of
15 the claimed invention.

 The claims are directed to or encompass “a receptor” (claim 17, line 13). There are no structural limitations to the receptor. The term “a receptor” encompasses a genus of compounds. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any
20 structural limitations on the genus. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The
25 general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to

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describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 19, SEQ ID NO: 20, or SEQ ID NO: 21 alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to
5 describe the genus. Thus, applicant was not in possession of the claimed genus. It is suggested that the claim 17 recite "said receptor."

Claims 17, 21, 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening for a compound that
10 changes the binding activity of said ligand for said receptor comprising the amino acid sequence of SEQ ID NO: 21, does not reasonably provide enablement for said method wherein said receptor comprises the amino acid sequence of SEQ ID NO: 19 or SEQ ID NO: 20. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention
15 commensurate in scope with these claims.

SEQ ID NO: 19 and SEQ ID NO: 20 are partial peptides of SEQ ID NO: 21. SEQ ID NO: 19 comprises amino acids 81-171 of SEQ ID NO: 21 and SEQ ID NO: 20 comprises amino acids 228-286 of SEQ ID NO: 21. Thus, SEQ ID NO: 19 and SEQ ID NO: 20 are also non-overlapping peptides of SEQ ID NO: 21. No evidence is provided
20 that the ligand binds either of SEQ ID NO: 19 or SEQ ID NO: 21. On the one hand, the skilled artisan is required to perform a screening method utilizing a ligand and a receptor that do not bind. On the other, the structures of SEQ ID NO: 19 and SEQ ID NO: 20 are unlimited beyond the recited sequence and the skilled artisan is left to randomly

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determine how to construct a polypeptide comprising the amino acid sequence of SEQ ID NO: 19 or SEQ ID NO: 20 that binds to the ligand. There is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (AF, cited by Applicants) page 1306, column 1, full paragraph 1, or Ngo (AG, cited by Applicants) page 433, full paragraph 1, and page 492, full paragraph 2. In view of the breadth of the claims, the lack of working examples, the limited amount of direction provided by the inventor, and the unpredictability in the art, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 17, 21, 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to or encompass a receptor polypeptide comprising the amino acid sequence of SEQ ID NO: 19 or SEQ ID NO: 20. SEQ ID NO: 19 and SEQ ID NO: 20 are partial peptides of SEQ ID NO: 21. SEQ ID NO: 19 comprises amino acids 81-171 of SEQ ID NO: 21 and SEQ ID NO: 20 comprises amino acids 228-286 of SEQ ID NO: 21. Thus, SEQ ID NO: 19 and SEQ ID NO: 20 are also non-overlapping peptides of SEQ ID NO: 21. The structures of SEQ ID NO: 19 and SEQ ID NO: 20 are unlimited beyond the recited amino acid sequence. No evidence is provided that the

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ligand binds either of SEQ ID NO: 19 or SEQ ID NO: 21. The specification and claim do not indicate what distinguishing attributes are shared by the members of the genus of the polypeptides comprising the amino acid sequence of SEQ ID NO: 19 or SEQ ID NO: 20 that are responsible for binding to the ligand. The specification and claim do not place
5 any limit on the number or type of amino acids that may be added to SEQ ID NO: 19 or SEQ ID NO: 20. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common
10 structural attributes responsible for ligand binding identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 21 alone is
15 insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

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Conclusion

No claims are allowable. Claim 23 is objected to as being dependent upon a rejected base claim. Claims limited to SEQ ID NO: 21 would be allowable assuming that the claim objections are overcome.

5 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

10 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

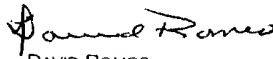
AFTER FINAL (703) 872-9307

15 IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

20 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

25 
DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

30 DSR
JANUARY 14, 2004